

REMARKS/ARGUMENTS

The Office Action of September 13, 2007 has been carefully reviewed and this paper is Applicants' response thereto. Claims 1-11, 13-21, 23, 28-29, 32, 37-38 and 43-46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,128,538 to Fischell *et al.* (Fischell), in view of U.S. Patent No. 6,618,617 to Chen *et al.* (Chen). Claims 1-11, 13-21, 23, 28-29, 32, 37-38 and 43-48 are pending in the application. Claims 1, 14, 28, 29, 32, 37, 38, 43, and 45 have been amended. Claims 47-48 are new. In response, Applicants respectfully traverse the rejections in view of the above amendments and the following remarks.

Amended Claims

Claims 1, 14, 28, 29, 32, 37, 38, 43, and 45 have been amended. Claim 1 has been amended to recite the features "the therapy device including a seizure detection algorithm for processing the neurological signal" and to further recite the feature "wherein the predetermined quantity of block counts is configured to allow the seizure detection algorithm to stabilize." Support for this is at least found in the specification as filed on pg. 44, paragraph [137] – pg. 46, paragraph [144], thus no new matter was added. Claims 14, 43 and 45 have been similarly amended, and thus also add no new matter.

Claim 32 has been amended to recite the features "calculating parameters that will be used to control a stimulation ON time," and "providing programming information based on the calculated parameters." Support for this is at least found in the specification as filed on pg. 50 – 51, paragraph [158], thus no new matter was added.

Claims 28, 29, 37, and 38 have been amended to clarify the intended scope and add no new matter.

New Claims

Claims 47 and 48 are new. Support for the features recited in claims 47 and 48 are at least found in the specification as filed on pg. 45, paragraph [141], thus no new matter was added.

Rejection under 35 U.S.C. §103(a) – Fischell & Chen

Claims 11-11, 13-21, 23, 28-29, 32, 37-38 and 43-46 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Fischell in view of Chen. Claims 1, 14, 28, 29, 32, 37, 38, 43 and 45 are independent.

Amended independent claim 1 recites the features “the therapy device including a seizure detection algorithm for processing the neurological signal,” and “preventing the therapy device from delivering therapy to the patient for a predetermined quantity of block counts after the therapy device has been activated, wherein the predetermined quantity of block counts is configured to allow the seizure detection algorithm to stabilize.” Fischell discloses an event detection system that uses digital signal processing techniques to detect events. Col. 14, l. 8-25. The Office Action states, and Applicants agree, that Fischell does not disclose preventing therapy for a predetermined quantity of block counts after the therapy device is activated. Office Action, page 3, section 10. The Office Action relies on Chen for disclosing this feature. *Id.* Chen discloses an implantable cardiac device that in response to a patient therapy request, initiates a timing of a therapy delay period. Col. 7, l. 66 – Col. 8, l. 12. The Office Action contends that Chen discloses preventing the therapy from delivering therapy to the patient for a predetermined quantity of block counts. Office Action, page 4, section 12. However, even if Chen could be said to disclose a delay for a predetermined quantity of block counts, neither Fischell nor Chen disclose, teach, or suggest the feature of “preventing the therapy device from delivering therapy for a predetermined quantity of block counts after the therapy device has been activated, wherein the predetermined quantity of block counts is configured to allow the seizure detection algorithm to stabilize” as recited in claim 1. (Emphasis added.) Therefore, the combination of Fischell and Chen fail to disclose all the features of claim 1 and claim 1 is patentably distinct over Fischell in view of Chen.

Independent claims 14, 43 and 45 recite features similar to the features discussed above with respect to claim 1 and, therefore, are patentably distinct over Fischell in view of Chen for at least the reasons that claim 1 is patentably distinct.

Claims 2-11, 13, 15-20, 23, 44 and 46 depend from one of the independent claims 1, 14, 43 and 45 and, therefore, are patentably distinct for at least the reasons that the independent

claims 1, 14, 43 and 45 are patentably distinct and for the additional features recited therein.

Amended independent claims 28, 29, 37 and 38 recite features similar to the features “determining whether the programming information can result in delivery of therapy with a number of stimulations per detection being above a predetermined limit of stimulations per detection” and “preventing the therapy device from being configured according to the programming information if it could result in delivery of a number of stimulations per detection above the predetermined limit of stimulations per detection” recited by claim 28. The Office Action has grouped these claims with independent claim 1 and suggested they are obvious for reasons similar to the reasons the Examiner is using to rejection claim 1. The Office Action, however, has failed to provide any rationale for why these features, which are not recited in claim 1, can be considered obvious in view of Fischell and Chen. Furthermore, to date no Office Action has provided support for why Fischell or Chen can be said to disclose these additional features of claims 28, 29, 37, and 38 and these features are not recited in claims that were previously rejected based on the disclosure of Fischell and Chen. Therefore the Office Action fails to make a proper rejection under 35 U.S.C. § 102(e) without providing greater specificity. *See* MPEP 707.07(d).

Amended independent claim 32, recites the features of “calculating parameters that will be used to control a stimulation ON time” and “providing programming information based on the calculated parameters for configuring the therapy device to deliver therapeutic treatment to the body via the therapy delivery element.” The Office Action has failed to provide any support for the suggestion that either Fischell or nor Chen disclose, teach, or suggest “calculating parameters that will be used to control a stimulation ON time.” Furthermore, the cited references do not disclose, teach, or suggest “providing programming information based on the calculated parameters for configuring the therapy device to deliver therapeutic treatment to the body via the therapy delivery element.”

The Office Action contends that Fischell in view of Chen “teaches the claimed invention but does not disclose an error handling procedure for parameters based on inputted data.” Office Action, page 5, section 14. The Office Action states “It would have been obvious to one having ordinary skill in the art . . . to modify the therapy system as taught by Fischell in view of Chen,

with user configurable data and error handling since it was known in the art that when configuration data is calculated and entered either automatically or manually into a medical device that error handling is used to provide a fail safe so that the patient and device are not harmed.” Applicants note, however, that claim 32 does not merely recite “including a fail-safe” or some other generic method step, but instead recites the feature “determining whether the programming information can result in stimulation ON time being outside of an acceptable range of between 1 second and 24 hours” and further recites the feature “preventing the therapy device from being configured according to the programming information if it could result in the stimulation ON time being outside of the acceptable range.” Therefore, even if the Office Action did support its suggestion that the use of a fail safe was known, something the Office Action failed to do here, this would at most provide support for the general concept of including some sort of fail safe, without more. Plainly, such a general concept does not disclose the features recited in claim 32. Here, the Office Action fails to provide sufficient support for the general inclusion of a fail safe, let alone the features recited in claim 32. Therefore, the Office Action fails to make a *prima facie* case of obviousness with respect to claim 32. Applicants further note that the rejection of claims 28, 29, 37 and 38 also suffer the same deficiencies.

In addition to the above deficiency in the rejection of claim 32, the Office Action admits the recited range of 1 second to 24 hours is not disclosed but suggests, based on the reasoning of *In re Aller*, 105 USPQ 233, that once the general conditions are disclosed in the prior art, discovering the optimum or workable range is not patentable. This argument fails, however, because the Office Action admits that the general conditions are not disclosed in the prior art. In particular, the Office Action states that Fischell in view of Chen “does not disclose an error handling procedure for parameters based on the inputted data.” Indeed, the Office Action has at most provided support for the suggestion that it would be obvious to add some sort of fail safe to the combination of Fischell and Chen based on the allegation that using a fail safe with a medical device was known. This falls far short of showing that the general conditions were known, thus the rationale of *In re Aller* is simply inapplicable.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Appln No. 10/687,290

Response to Office Action mailed September 13, 2007

CONCLUSION

All rejections having been addressed, Applicants respectfully submit that the instant application is in condition for allowance, and respectfully solicit prompt notification of the same. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the number set forth below.

Respectfully submitted,

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